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11 IN THE UNITED STATES DISTRICT COURT
12 FOR THE NORTHERN DISTRICT OF CALIFORNIA

13 (SAN FRANCISCO DIVISION)

14 IN RE: BEXTRA AND CELEBREX
15 MARKETING SALES PRACTICES AND
16 PRODUCT LIABILITY LITIGATION

MDL No. 1699

CRB

17 TOM HILAMAN (FL);
18 LUCRETIA SHIVERS (NC);

Case No. **C 07 4383**

19 Plaintiff,

CIVIL COMPLAINT

20 v.

JURY TRIAL DEMANDED

21 PFIZER, INC., PHARMACIA
22 CORPORATION, G.D. SEARLE LLC, (FKA
23 G.D. SEARLE & CO.), and MONSANTO
24 COMPANY,

25 Defendants.

26
27 Plaintiffs Tom Hilaman and Lucretia Shivers by and through their counsel, bring this
28 action against Defendants PFIZER, INC., PHARMACIA CORP., MONSANTO COMPANY,
and G.D. SEARLE LLC. (hereinafter collectively "Defendants") and allege as follows:

I. PARTIES

1. This is an action for damages arising from Defendants' design, manufacture, sale,
testing, marketing, advertising, promotion, and/or distribution of the unsafe medication

1 Celecoxib, trade name CELEBREX® (“CELEBREX”).

2 2. Plaintiff Tom Hilaman was at all relevant times adult resident citizen of the State
3 of Florida, County of Leon. Plaintiff was prescribed and began taking CELEBREX for the
4 treatment of pain. As a direct and proximate result of using CELEBREX, Plaintiff suffered severe
5 cardiovascular injuries while taking CELEBREX, including, but not limited to, serious
6 cardiovascular injury or heart attack on or about October 8, 2003, which has caused and will
7 continue to cause Plaintiff damages and places Plaintiff at risk of further serious injury or death.

8 3. Plaintiff Lucretia Shivers was at all relevant times adult resident citizen of the
9 State of North Carolina, County of Vance. Plaintiff was prescribed and began taking CELEBREX
10 for the treatment of pain. As a direct and proximate result of using CELEBREX, Plaintiff suffered
11 severe cardiovascular injuries while taking CELEBREX, including, but not limited to, serious
12 cardiovascular injury or heart attack on or about October 12, 2004, which has caused and will
13 continue to cause Plaintiff damages and places Plaintiff at risk of further serious injury or death.

14 4. Defendant Pfizer Inc. (“Pfizer”) is a Delaware corporation with its principal place
15 of business in New York, New York. In 2003, Pfizer acquired Pharmacia Corporation for nearly
16 \$60 billion. At all relevant times Pfizer and/or its predecessors in interest were engaged in the
17 business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, and
18 selling the drug Celecoxib, under the trade name CELEBREX in California and nationwide.

19 5. Defendant G. D. Searle, LLC, formerly known as G. D. Searle & Co. (“Searle”) is
20 a Delaware corporation with its principal place of business in Illinois. At all relevant times,
21 Searle has been engaged in the business of marketing and selling CELEBREX nationwide and in
22 California. Searle is a subsidiary of Pfizer, acting as its agent and alter ego in all matters alleged
23 within this Complaint.

24 6. Defendant Monsanto Company (“Monsanto”) was the parent corporation of Searle
25 and is a Delaware corporation. At all times relevant hereto, Monsanto, through its subsidiary
26 companies, was in the business of manufacturing, marketing, selling and distributing the
27 pharmaceutical product CELEBREX nationwide.

28 7. Defendant Pharmacia Corporation (“Pharmacia”) is a Delaware corporation with

1 its principal place of business in New Jersey. At all relevant times, Pharmacia, and its
2 predecessors in interest have been engaged in the business of designing, testing, manufacturing,
3 packaging, marketing, distributing, promoting, and selling CELEBREX nationwide and in
4 California.

5 6 **II. JURISDICTION AND VENUE**

7 8. This is an action for damages, which exceeds seventy-five thousand dollars
8 (\$75,000.00).

9 9. There is complete diversity of citizenship between the Plaintiffs and Defendants.
10 This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C.A. § 1332
11 (diversity jurisdiction) because the amount in controversy exceeds \$75,000.00, and because there
12 is complete diversity of citizenship between Plaintiffs and Defendants.

13 10. Venue is proper in this United States Judicial District pursuant to 28 U.S.C.A.
14 § 1391. Defendants marketed, advertised and distributed the dangerous product in the district,
15 thereby receiving substantial financial benefit and profits the dangerous product in this district,
16 and reside in this district under 28 U.S.C.A. § 1391(c), such that venue is proper.

17 11. At all relevant times herein, Defendants were in the business of designing,
18 manufacturing, marketing, developing, testing, labeling, promoting, distributing, warranting and
19 selling their product, CELEBREX. Defendants at all times relevant hereto designed, developed,
20 manufactured, promoted, marketed, distributed, tested, warranted and sold in interstate commerce
21 the aforementioned prescription drug. Defendants do substantial business Nationwide and within
22 this Federal Judicial District, advertise in this district, receive substantial compensation and
23 profits from sales of CELEBREX in this District, and made material omissions and
24 misrepresentations and breaches of warranties in this District so as to subject them to *in personam*
25 jurisdiction in this District. In engaging in the conduct alleged herein each defendant acted as the
26 agent for each of the other defendants, or those defendant's predecessors in interest.

27 **III. INTERDISTRICT ASSIGNMENT**

28 12. Assignment to the San Francisco Division is proper as this action is related to *In*
Re: Celebrex and Celebrex Marketing Sales Prac. and Pro. Liab. Lit., MDL-1699, assigned to the

1 Honorable Charles R. Breyer by the Judicial Panel on Multidistrict Litigation on September 6,
2 2005. (See also, MDL-1699 Pretrial Order No. 2)

3 **IV. FACTUAL BACKGROUND**

4 **A. Facts Regarding All Plaintiffs**

5
6 13. Plaintiffs and Plaintiffs' healthcare providers were at the time of Plaintiffs' injuries
7 unaware - and could not have reasonably known or have learned through reasonable diligence -
8 that such injury directly resulted from Defendants' negligent and otherwise culpable acts,
9 omissions, and misrepresentations or from Plaintiffs' ingestion of CELEBREX.

10 14. Plaintiffs used CELEBREX in a proper and reasonably foreseeable manner and
11 used it in a condition that was substantially the same as the condition in which it was
12 manufactured and sold.

13 15. Plaintiffs would not have used CELEBREX had Defendants properly disclosed the
14 risks associated with the drug.

15 **B. Facts Regarding CELEBREX: Science and other Cox-2 Inhibitors**

16
17 16. CELEBREX is one of a class of pain medications called non-steroidal anti-
18 inflammatory drugs ("NSAIDs"). Aspirin, naproxen (trade name Aleve), and ibuprofen (trade
19 name Advil) are examples of well-known NSAIDs.

20 17. NSAIDs reduce pain by blocking the body's production of pain transmission
21 enzymes called cyclo-oxygenase or "COX." There are two forms of COX enzymes—COX-1 and
22 COX-2. Aspirin, naproxen and ibuprofen all act by blocking COX-1 and COX-2 enzymes.

23 18. In addition to decreasing In addition to decreasing inflammation, the
24 prostaglandins that are supported by COX-1 enzymes are involved in the production of gastric
25 mucus; this protects the stomach wall from the hydrochloric acid present in the stomach. It is
26 generally accepted in the medical community that by blocking the COX-1 enzyme, the body's
27 ability to protect gastric tissue is hampered and as a result, can cause harmful gastrointestinal side
28 effects, including stomach ulceration and bleeding.

1 19. Prosagalin I2 is the predominant cyclooxygenase product in endothelium,
2 inhibiting platelet aggregation (preventing clot formation), causing vasodilation, and preventing
3 the proliferation of vascular smooth muscle. Whereas older NSAIDS inhibit Thromboxane A2
4 and Prostaglandin I2, the COX-2 inhibitors leave Thromboxane A2 unaffected. Thromboxane A2
5 is a potent platelet aggregator and vasoconstrictor which is synthesized by platelets. Therefore,
6 while the older NSAIDS suppress platelet aggregation and vasoconstriction, the COX-2 inhibitors
7 support it.

9 20. Traditional NSAIDs like aspirin reduce pain/inflammation and therefore pain by
10 inhibiting both COX-1 and COX-2 enzymes simultaneously. As would be expected, traditional
11 NSAIDs may cause ulcers in the stomach. However, traditional NSAIDs do not cause blood
12 clots, rather they actually reduce the risk of clots and help protect heart function.

14 21. Defendants and other pharmaceutical companies set out to remedy these ulcer and
15 bleeding problems suffered by some NSAID users by developing “selective” inhibitors that
16 would block only COX-2 production, thus (supposedly) allowing the proper maintenance of
17 gastric tissue while still reducing inflammation.

19 22. In making this decision, Defendants and their predecessors in interest either
20 intentionally ignored or recklessly disregarded current medical knowledge that selective COX-2
21 inhibition lowers prostacyclin levels and causes thromboxane A₂ to be uninhibited, causing blood
22 clots, and giving rise to various clot-related cardiovascular events, including heart attack, stroke,
23 unstable angina. The vasoconstriction and fluid retention cause the hypertension.

1 23. Pfizer launched CELEBREX, the first of the three major COX-2 inhibitor drugs, in
2 January 1999 and initiated a massive marketing campaign to convince doctors and consumers of
3 the superiority of their new “blockbuster” drug over less inexpensive NSAIDs. In May, 1999,
4 Merck & Co., Inc. (“Merck”) launched Vioxx, its own selective COX-2 inhibitor.
5

6 24. Seeking increased market share in this extremely lucrative market, Defendants,
7 and their predecessors in interest, also sought approval of a “second generation” selective COX-2
8 inhibitor and filed for FDA approval of Celecoxib (Celebrex) on January 16, 2001 for the
9 (i) prevention and treatment of acute pain, (ii) treatment of primary dysmenorrhea, and (iii) relief
10 of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis.
11

12 C. Facts Regarding CELEBREX’s Safety and Defendants’ Knowledge Thereof
13

14 25. The potential for cardiovascular risk of selective COX-2 inhibitors was known to
15 Defendants long before the market launch. By 1997, and prior to the submission of the New
16 Drug Application (the “NDA”) for CELEBREX, Defendants was aware that, by inhibiting COX-
17 2, CELEBREX altered the homeostatic balance between prostacyclin synthesis and thromboxane
18 and thereby, increased the prothrombotic effects of the drugs, causing blood clots to form in those
19 who ingested it. *See Topol, E.J., et al., Risk of Cardiovascular Events Associated with Selective*
20 *Cox-2 Inhibitors, JAMA, August 22, 2001 at 954.*
21

22 26. As Pharmacologist, Dr. Garrett Fitzgerald, of the University of Pennsylvania,
23 reported in an editorial published in *The New England Journal of Medicine* on October 21, 2004,
24 that it was known as early as 1999 that selective COX-2 inhibitors, such as CELEBREX,
25 suppressed the formation of prostaglandin I-2 in healthy volunteers, inhibited platelet aggregation
26 in vitro, and may predispose patients to myocardial infarction or thrombotic stroke.
27
28

1 27. Based on the studies performed on CELEBREX, other COX-2 inhibitors, and
2 basic research on this type of selective inhibitor which had been widely conducted, Defendants
3 knew when CELEBREX was being developed and tested that selective COX-2 inhibitors posed
4 serious cardiovascular risks for anyone who took them, and presented a specific additional threat
5 to anyone with existing heart disease or cardiovascular risk factors. Studies show that selective
6 COX-2 inhibitors, including CELEBREX, decrease blood levels of a prostacyclin. When those
7 levels fall, the arteries are more vulnerable to clotting, high blood pressure, heart attack, and
8 stroke.
9

10
11 28. Despite years of studies on selective COX-2 inhibitors, as well as the disturbing
12 new studies specifically analyzing the risks of CELEBREX, Defendants failed to take any action
13 to protect the health and welfare of patients, but instead, continued to promote the drug for sale
14 even after the FDA's Drug Safety and Risk Management Advisory Committee and Arthritis Drug
15 Advisory Committee meetings.
16

17 **1. CELEBREX and Cox-2 Studies Did Not Show CELEBREX to be Safe**

18 29. The defendants touted the CELEBREX Long-Term Arthritis Safety Study
19 ("CLASS") as the primary evidence to support its theory that CELEBREX was safer for
20 consumers that could not tolerate traditional NSAIDs in their gastrointestinal system. (CLASS
21 data is found in NDA 20-998/S-009 submitted to the FDA by G.D. Searle on June 12, 2000.
22 CLASS was submitted to the FDA on June 12, 2000 and reviewed by James Witter, M.D., Ph.D.
23 (FDA Medical Officer) on September 20, 2000.)
24

25 **2. CLASS**

26 30. The FDA Medical Officer Review of the CLASS data proves CELEBREX is no
27 more efficacious than other traditional NSAIDS and is harmful to consumers. See generally,
28

1 FDA Medical Officer Review, NDA 20-998/S-009 submitted to the FDA by G.D. Searle on
2 June 12, 2000 ("FDA CLASS Review"). On April 7, 2005, the FDA issued an *Alert* noting only
3 minimal information is available regarding CELEBREX: "The only available data from a long
4 term comparison of CELEBREX to other NSAIDs came from the CLASS study...."

5
6 31. Pfizer misrepresented the data in CLASS by using biased authors. According to
7 the *Washington Post* the CLASS authors were either employees of Pharmacia, CELEBREX's
8 manufacturer, or paid consultants of the company. Pfizer needed a study to demonstrate that its
9 Cox-2 inhibitor was safer for the stomach than older cheaper medications: CLASS was designed
10 to be that study. Unfortunately, the results of the completed study revealed the truth –
11 CELEBREX offered no gastrointestinal (GI) benefit. Instead of releasing the complete –12-
12 month – results from CLASS, Pfizer had only the first six months of data published in the *Journal*
13 *of American Medicine*. JAMA 2000;48:1455-1460.
14

15
16 32. "After reviewing the full study, the FDA's arthritis advisory committee concluded
17 that CELEBREX offers no proven safety advantage over the two older drugs in reducing the risk
18 of ulcer complications, said FDA spokesman Susan Cruzan." *Washington Post*, August 5, 2001.
19 According to the FDA's review of the CLASS data: "Celecoxib did not demonstrate any
20 statistical superiority to NSAIDs (pooled) or either comparator (diclofenac and ibuprofen) with
21 regards to the primary safety endpoint of CSUGIE (Clinically Significant Upper Gastrointestinal
22 Adverse Events) at any point in the trial although there were trends that favored celecoxib" (FDA
23 CLASS Review)

24 33. According to an August 5, 2001 article in the *Washington Post*, editors of the
25 *Journal of the American Medical Association* (JAMA) and other medical experts, "were
26 flabbergasted" when they realized they had been duped by only being provided with the first six
27 months of CLASS data. The *Washington Post* reported JAMA editors as saying: "When all of the
28 data were considered, most of CELEBREX's apparent safety advantage disappeared."

1 34. The “scientific double-cross” boosted sales. “[T]he JAMA article and editorial
2 have likely contributed to CELEBREX’s huge sales. ‘When the JAMA article comes out and
3 confirms the hype, that probably has more impact than our labeling does,’ said Robert J. Temple,
4 director of medical policy at the FDA’s Center for Drug Evaluation and Research.” *Washington*
5 *Post*, August 5, 2001.

6 35. “A total of 36 deaths occurred during the [CLASS] study or during post study
7 follow-up: 19 in the celecoxib group, 9 in the diclofenac group and 8 in the ibuprofen group
8 Most deaths were cardiovascular in nature.” FDA CLASS Review, at 54. The increased number
9 of adverse cardiovascular events in the CELEBREX group was not surprising as they were also
10 revealed in the original New Drug Application (NDA) submitted for CELEBREX. “In the
11 original NDA, myocardial infarction was noted to occur at a higher rate in celecoxib-treated as
12 compared to placebo treated patients. In the long term trial (Trial 024) that was included in the
13 NDA submission, the predominate (>90%) cause of death for patients taking celecoxib at any
14 does was cardiovascular.” FDA CLASS Review at 78.

15 36. Public Citizen, a public watchdog organization, reviewed the CLASS data in its
16 entirety. A complete review reveals the combined anginal adverse events were 1.4% in celecoxib
17 (CELEBREX) group versus 1.0% in either NSAID group. Specifically, the rate of heart attack in
18 the CELEBREX was double that of the other two NSAIDs, 0.2% vs. 0.1%, respectively.

19 37. The CLASS data proves that Pfizer knew that its first generation Cox-2 inhibitor,
20 CELEBREX, caused a disproportionately and statistically significantly high number of adverse
21 cardiovascular events before it was introduced to the market in January 1999. According to
22 Public Citizen, after CLASS, the FDA recommended a trial to specifically assess the CV risk of
23 COX-2 inhibitors. The Adenoma Prevention with Celecoxib (APC) trial was intended to be this
24 placebo-controlled trial of CELEBREX.

25 3. APC Trial

26 38. The Adenoma Prevention with Celecoxib (APC) trial compared the efficacy and
27 safety of celecoxib with placebo. N.ENG. J. MED. 352;11 at 1072. According to the APC trial, the
28 number of deaths from cardiovascular causes was significantly higher in the CELEBREX group

1 when compared to placebo. (0.1% placebo; 0.4% CELEBREX 200mg; and 0.9% CELEBREX
2 400mg). *Id.* at 1075.

3 39. The FDA Reported the APC data as follows¹:

4
5 In the National Cancer Institute's Adenoma Prevention with
6 Celecoxib (APC) trial in patients at risk for recurrent colon polyps,
7 a 2-3 fold increased risk of serious adverse CV events was seen for
8 CELEBREX compared to placebo after a mean duration of
9 treatment of 33 months. There appeared to be a dose response
10 relationship, with a hazard ratio of 2.5 for CELEBREX 200 mg
twice daily and 3.4 CELEBREX 400 mg twice daily for the
composite endpoint of death from CV causes, myocardial infarction
(MI), or stroke.

11 40. The dosage noted in the study is important for two reasons: first, there appears to
12 be an association between dosage and the increase in adverse cardiovascular events. See
13 generally, at 1077. Second, most patients increase dosage. Pfizer knew patients were increasing
14 their dosages as noted in CLASS: "Interestingly ... up to 70% of patients increased their dose for
15 celecoxib." FDA CLASS Review at 74. Thus, Pfizer was aware of the dosage creep.

16 4. Other CELEBREX Trials

17 41. Several other CELEBREX trials also gave Defendants insight into the
18 cardiovascular risks presented by CELEBREX. The Prevention of Spontaneous Adenomatous
19 Polyps (PreSAP) trial identified the death rate from cardiovascular causes (heart attack, stroke,
20 heart failure, angina, or need for CV procedure) as 3.6% with CELEBREX as compared to 2.7%
for placebo.

21 42. Public Citizen also reviewed the results of Study IQ IQ5-97-02-001 which
22 reflected "the combined rate of all serious cardiovascular adverse events in patients getting a
23 placebo was 2.1% but was greatly increased in those getting celecoxib to 7.7%, a 3.6 fold
24 increase in CV risk in those people taking celecoxib. (p=0.03)"². According to Dr. Sidney Wolfe,
25 "The study revealed a significantly increased rate (3.6-fold) of serious CV adverse events and
26 more than a doubling in the rate of CV deaths in people using celecoxib compared to those using
27

28 ¹ April 7, 2005 FDA Alert: www.fda.gov/cder/drug/infopage/CELEBREX/CELEBREX-hcp.htm.

² *Public Citizen*, January 26, 2005, Dr. Sidney M. Wolfe.

1 placebo.”³

2 **5. Cox-2 Studies: VIGOR and APPROVe**

3 43. Pfizer also had access to other data which indicated a cardiovascular risk with its
4 drugs. Specifically, Pfizer had knowledge of two studies conducted by Merck related to its Cox-2
5 inhibitor Vioxx – Vioxx Gastrointestinal Outcomes Research (VIGOR) and Adenomatous Polyp
6 Prevention (APPROVe).

7 **a. VIGOR**

8 44. In 2000, The FDA Medical Officer Review of CLASS specifically noted the
9 VIGOR trial and the concern over serious adverse cardiovascular events. FDA CLASS Review at
10 78.

11 45. According to VIGOR (near acronym for Vioxx Gastrointestinal Outcomes
12 Research) Vioxx patients experienced 20% more serious clinical adverse events (statistically
13 significant); they experienced 4.6 times more hypertension events serious enough to warrant
14 discontinuation, 1.7 times more edema events, and 1.85 times as many congestive heart failure
15 adverse events. By two measures of cardiovascular events related to blood clots, Vioxx had twice
16 the risk of naproxen and the results were considered statistically significant.

17 46. The VIGOR study comprised the most definitive scientific evidence ever obtained
18 about pharmaceutical products. It was a large, randomized clinical trial, the gold standard of
19 medical research. It was a safety study with endpoints set in advance. As Merck stated many
20 times, it was designed to provide definite proof of safety, convincing enough to silence the most
21 skeptical critics. In medical terms, the VIGOR results raised the question of whether selective
22 inhibition of Cox-2 was a monumental mistake from the start. While the NSAID risks to the GI
23 system were real and sometimes fatal, they were dwarfed by the cardiovascular risks of the
24 arthritis population that needed these drugs on a daily basis. All makers of NSAIDs, including
25 Defendants, were aware of these results.

26 **b. APPROVe**

27 47. Anxious to put safety questions surrounding Vioxx to rest, Merck designed

28 ³ Id.

1 another large scale trial, Adenomatous Polyp Prevention (APPROVe), which was intended to test
2 the drug's ability to prevent or shrink colon polyps, but would also compare the cardiovascular
3 safety of Vioxx to a placebo control. According to the analysis conducted by Public Citizen of
4 the APPROVe data: Vioxx "doubled the risk of any thrombotic cardiovascular event" and
5 "doubled the risk of MI (myocardial infarction a/k/a heart attack)⁴. *Public Citizen*, January 24,
6 2005, at 15. Despite the available CELEBREX data and other information related to Vioxx,
7 Pfizer never paused to re-evaluating the CELEBREX data and studies.

8
9 48. The scientific data available during and after CELEBREX's approval process
10 made clear to Defendants that their formulation of CELEBREX would cause a higher risk of
11 blood clots, stroke and/or myocardial infarctions among CELEBREX consumers, alerting them to
12 the need to do additional and adequate safety studies.

13 49. As stated by Dr. Topol on October 21, 2004, in *The New England Journal of*
14 *Medicine*, outlining Defendants' failure to have conducted the necessary trials before marketing
15 to humans "... it is mandatory to conduct a trial specifically assessing cardiovascular risk and
16 benefit of (COX-2 inhibitors). Such a trial needed to be conducted in patients with established
17 coronary artery disease, who frequently have coexisting osteoarthritis requiring medication and
18 have the highest risk of further cardiovascular events."

19 50. Dr. Topol was also the author on the study published in August 2001 in JAMA
20 (listed above) that reported an increased risk of thrombotic cardiovascular events in persons who
21 used COX-2 inhibitors.

22 51. Based upon readily available scientific data, Defendants knew, or should have
23 known, that their pre-approval testing of CELEBREX did not adequately represent the cross-
24 section of individuals who were intended consumers and therefore, likely to take CELEBREX.
25 Therefore, Defendants' testing and studies were grossly inadequate.

26
27 ⁴ Although Merck claims that the two-fold risk of heart attacks and strokes seen in the APPROVe trial did
28 not emerge until after patients had been taking the drug for 18 months, closer analysis indicates that significant
increase in risk of heart attack was evident in as little as 4 months time.

1 52. Had Defendants done adequate testing prior to approval and “market launch,”
2 rather than the extremely short duration studies done on the small size patient base that was
3 actually done the defendants’ scientific data would have revealed significant increases in
4 incidence of strokes and myocardial infarctions among the intended and targeted population of
5 CELEBREX consumers. Adequate testing would have shown that CELEBREX possessed
6 serious side effects. Defendants should have taken appropriate measures to ensure that their
7 defectively designed product would not be placed in the stream of commerce and/or should have
8 provided full and proper warnings accurately and fully reflecting the scope and severity of
9 symptoms of those side effects should have been made.

10 53. In fact, post-market approval data did reveal increased risks of clotting, stroke and
11 myocardial infarction, but Defendants intentionally suppressed this information in order for them
12 to gain significant profits from continued CELEBREX sales.

13 54. Defendants’ failure to conduct adequate testing and/or additional testing prior to
14 “market launch” was based upon their desire to generate maximum financial gains for themselves
15 and to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.

16 55. At the time Defendants manufactured, advertising, and distributed CELEBREX to
17 consumers, Defendants intentionally or recklessly ignored and/or withheld information regarding
18 the increased risks of hypertension, stroke and/or myocardial infarctions because Defendants
19 knew that if such increased risks were disclosed, consumers would not purchase CELEBREX, but
20 instead would purchase other cheaper and safer NSAIDs.

21 **D. Facts Regarding Defendants’ Marketing and Sale of CELEBREX**

22 56. Such an ineffective and unreasonably dangerous drug could only be widely
23 prescribed as a result of a tremendous marketing campaign. In addition to being aggressive, the
24 Defendants’ marketing campaign was fraudulent and misleading. But for fraudulent and
25 misleading advertising, consumers, including the Plaintiff, would not have purchased
26 CELEBREX, a more costly prescriptive drug, ineffective for its intended purposes.

27 57. On January 10, 2005 the FDA issued Pfizer a written reprimand for its
28 promotional activities. The reprimand reads: “These five promotional pieces [3 CELEBREX and

1
2 Celebrex] variously: omit material facts ... and make misleading safety, unsubstantiated
3 superiority, and unsubstantiated effectiveness claims.” This was not the Defendants first offense
4 related to its Cox-2 inhibitors. The FDA also reprimanded Pfizer on October 6, 1999 noting:
5 “DDMAC has reviewed these promotional pieces and has determined that they are false or
6 misleading because they contain unsubstantiated comparative claims, misrepresentations of
7 CELEBREX’s safety profile, and are lacking in fair balance.” Ultimately, on April 8, 2005, the
8 New York Times reported the results of an FDA advisory panel: “The February advisory panel
9 voted overwhelmingly that the company should never again advertise the drug [CELEBREX].”

10 58. At all times relevant herein, Defendants engaged in a marketing campaign with the
11 intent that consumers would perceive CELEBREX as a safer and better drug than its other
12 NSAIDs and, therefore, purchase CELEBREX.

13 59. Defendants widely and successfully marketed CELEBREX throughout the United
14 States by, among other things, conducting promotional campaigns that misrepresented the
15 efficacy of CELEBREX in order to induce a widespread use and consumption. CELEBREX was
16 represented to aid the pain and discomfort of arthritis, osteoarthritis, and related problems.
17 Defendants made misrepresentations by means of media advertisements, and statements
18 contained in sales literature provided to Plaintiff’s prescribing physicians.

19 60. Despite knowledge of the dangers presented by CELEBREX, Defendants and
20 Defendants’ predecessors in interest, through their officers, directors and managing agents for the
21 purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to remedy
22 the known defects of Defendants’ product, CELEBREX, and failed to warn the public, including
23 Plaintiff, of the serious risk of injury occasioned by the defects inherent in Defendants’ product,
24 CELEBREX. Defendants and their officers, agents and managers intentionally proceeded with
25 the inadequate safety testing, and then the manufacturing, sale and marketing of Defendants’
26 product, CELEBREX, knowing that persons would be exposed to serious potential danger, in
27 order to advance their own pecuniary interests. Defendants’ conduct was wanton and willful, and
28 displayed a conscious disregard for the safety of the public and particularly of Plaintiff.

1 61. In an elaborate and sophisticated manner, Defendants aggressively marketed
2 CELEBREX directly to consumers and medical professionals (including physicians and leading
3 medical scholars) in order to leverage pressure on third party payors, medical care organizations,
4 and large institutional buyers (*e.g.*, hospitals) to include CELEBREX on their formularies. Faced
5 with the increased demand for the drug by consumers and health care professionals that resulted
6 from Defendants' successful advertising and marketing blitz, third party payors were compelled
7 to add CELEBREX to their formularies. Defendants' marketing campaign specifically targeted
8 third party payors, physicians, and consumers, and was designed to convince them of both the
9 therapeutic and economic value of CELEBREX.

10 62. Defendants represented that CELEBREX was similar to ibuprofen and naproxen
11 but was superior because it lacked any of the common gastrointestinal adverse side effects
12 associated with these and other non-steroidal anti-inflammatory drugs ("NSAIDS"). For instance,
13 NSAIDS can, in certain patients, cause gastrointestinal perforations, ulcers and bleeding with
14 long-term use. Defendants promoted CELEBREX as a safe and effective alternative that would
15 not have the same deleterious and painful impact on the gut, but that would be just as effective, if
16 not more so, for pain relief.

17 63. CELEBREX possessed dangerous and concealed or undisclosed side effects,
18 including the increased risk of serious cardiovascular events, such as heart attacks, unstable
19 angina, cardiac clotting, deep vein thrombosis, hypertension, and cerebrovascular events, such as
20 strokes. In addition, CELEBREX was no more effective than traditional and less expensive
21 NSAIDs and, just like traditional NSAIDs, carried a risk of perforations, ulcers, and
22 gastrointestinal bleeding. Defendants chose not to warn about these risks and dangers.

23 64. Defendants knew of these risks before the U.S. Food and Drug Administration (the
24 "FDA") approved CELEBREX for sale, but Defendants ignored, downplayed, suppressed,
25 omitted, and concealed these serious safety risks and denied inefficacy in its promotion,
26 advertising, marketing, and sale of CELEBREX. Defendants' omission, suppression, and
27

1 concealment of this important information enabled CELEBREX to be sold to, and purchased, or
2 paid for by, the Consumers at a grossly inflated price.

3 65. Consequently, CELEBREX captured a large market share of anti-inflammatory
4 drugs prescribed for and used by patients. In 2004 alone, sales of CELEBREX exceeded \$2
5 billion, despite the significantly higher cost of CELEBREX as compared to other pain relievers in
6 the same family of drugs.

7 66. Because Defendants engaged in a promotional and marketing campaign that
8 featured an advertising blitz directly targeted to consumers, that touted CELEBREX as a safer
9 drug than other drugs in its class, while uniformly failing to disclose the health risks of
10 CELEBREX, Defendants were able to justify pricing CELEBREX significantly higher than the
11 cost of generic aspirin. In reality, that price inflation was not justified. Had Defendants disclosed
12 the truth about CELEBREX, Defendants would not and could not have reaped the billions of
13 dollars in CELEBREX sales that were achieved as a direct result of the concealment, omission,
14 suppression, and obfuscation of the truth.

15 67. The Defendants intentionally, deliberately, knowingly, and actively concealed,
16 omitted, suppressed, and obfuscated important and material information regarding the risks,
17 dangers, defects, and disadvantages of CELEBREX from Plaintiff, the public, the medical
18 community, and the regulators. This concealment and omission was deliberate, knowing, active,
19 and uniform, was intended to induce and maximize sales and purchases of CELEBREX, and
20 prevented Plaintiff from obtaining all the material information that would be important to their
21 decisions as reasonable persons to purchase, pay for, and/or use CELEBREX.

22 68. Defendants' systematic, active, knowing, deliberate, and uniform concealment,
23 omissions, suppression, and conduct caused Plaintiff to purchase, pay for, and/or use
24 CELEBREX; and caused Plaintiff's losses and damages as asserted herein.

25 69. Had Defendants done adequate testing prior to approval and "market launch," the
26 defendants' scientific data would have revealed significant increases in stroke and myocardial
27 infarction amongst the intended population of CELEBREX consumers. Adequate testing would
28

1 have shown that CELEBREX possessed serious side effects. Defendants should have taken
2 appropriate measures to ensure that their defectively designed product would not be placed in the
3 stream of commerce and/or should have provided full and proper warnings accurately and fully
4 reflecting the scope and severity of symptoms of those side effects should have been made.

5 70. In fact, post-market approval data did reveal increased risks of clotting, stroke and
6 myocardial infarction, but Defendants intentionally suppressed this information in order for them
7 to gain significant profits from continued CELEBREX sales.

8 71. Defendants' failure to conduct adequate testing and/or additional testing prior to
9 "market launch" was based upon their desire to generate maximum financial gains for themselves
10 and to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.

11 72. At the time Defendants manufactured, advertising, and distributed CELEBREX to
12 consumers, Defendants intentionally or recklessly ignored and/or withheld information regarding
13 the increased risks of hypertension, stroke and/or myocardial infarctions because Defendants
14 knew that if such increased risks were disclosed, consumers would not purchase CELEBREX, but
15 instead would purchase other cheaper and safer NSAID drugs.

16 **CLAIMS FOR RELIEF**

17 **FIRST CLAIM FOR RELIEF**

18 **Negligence**

19 73. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if
20 fully set forth herein and further allege as follows.

21 74. Defendants owed Plaintiffs a duty to exercise reasonable care when designing,
22 manufacturing, marketing, advertising, distributing, and selling CELEBREX. This duty included
23 the duty not to introduce a pharmaceutical drug, such as CELEBREX, into the stream of
24 commerce that caused users to suffer from unreasonable, dangerous or untoward adverse side
25 effects.
26

27 75. At all relevant times to this action, Defendants owed a duty to properly warn
28 Plaintiffs and the Public of the risks, dangers and adverse side effects of their pharmaceutical

1 drug CELEBREX.

2 76. Defendants breached their duties by failing to exercise ordinary care in the
3 preparation, design, research, testing, development, manufacturing, inspection, labeling,
4 marketing, promotion, advertising and selling of CELEBREX, including: failing to use due care
5 in the preparation and development of CELEBREX to prevent the aforementioned risk of injuries
6 to individuals when the drugs were ingested;

7 a. failing to use due care in the design of CELEBREX to prevent the aforementioned
8 risk of injuries to individuals when the drugs were ingested;

9
10 b. failing to conduct adequate pre-clinical testing and research to determine the safety
11 of CELEBREX;

12
13 c. failing to conduct adequate post-marketing surveillance and exposure studies to
14 determine the safety of CELEBREX;

15
16 d. failing to completely, accurately and in a timely fashion, disclose the results of the
17 pre-marketing testing and post-marketing surveillance and testing to Plaintiffs, consumers, the
18 medical community, and the FDA;

19
20 e. failing to accompany CELEBREX with proper warnings regarding all possible
21 adverse side effects associated with the use of CELEBREX;

22
23 f. failing to use due care in the manufacture, inspection, and labeling of CELEBREX
24 to prevent the aforementioned risk of injuries to individuals who used CELEBREX;

25
26 g. failing to use due care in the promotion of CELEBREX to prevent the
27 aforementioned risk of injuries to individuals when the drugs were ingested;

28

1 h. failing to use due care in the sale and marketing of CELEBREX to prevent the
2 aforementioned risk of injuries to individuals when the drugs were ingested;

3
4 i. failing to use due care in the selling of CELEBREX to prevent the aforementioned
5 risk of injuries to individuals when the drugs were ingested;

6
7 j. failing to provide adequate and accurate training and information to the sales
8 representatives who sold CELEBREX;

9
10 k. failing to provide adequate and accurate training and information to healthcare
11 providers for the appropriate use of CELEBREX; and

12 l. being otherwise reckless, careless and/or negligent.
13

14 77. Despite the fact that Defendants knew or should have known that CELEBREX
15 caused unreasonable and dangerous side effects which many users would be unable to remedy by
16 any means, Defendants continued to promote and market CELEBREX to consumers, including
17 Plaintiffs, when safer and more effective methods of pain relief were available.
18

19 78. Defendants were, or should have been, had they exercised reasonable care, in
20 possession of evidence demonstrating that CELEBREX caused serious side effects. Nevertheless,
21 they continued to market their products by providing false and misleading information with
22 regard to the safety and efficacy of CELEBREX.
23

24 79. Defendants knew or should have known that consumers such as Plaintiffs would
25 foreseeably suffer injury as a result of their failure to exercise ordinary care as described above.
26
27
28

1 80. As a direct and proximate consequence of Defendants' acts, omissions, and
2 misrepresentations described herein, Plaintiffs sustained serious injuries and related losses.
3 Plaintiffs required and will continue to require healthcare and services. Plaintiffs have incurred
4 and will continue to incur medical and related expenses. Plaintiffs also have suffered and will
5 continue to suffer mental anguish, physical pain and suffering, diminished capacity for the
6 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of
7 preexisting conditions and activation of latent conditions, and other losses and damages.
8 Plaintiffs also incurred direct medical losses and costs include care for hospitalization, physician
9 care, monitoring, treatment, medications, and supplies. Plaintiffs have also suffered loss of wages.
10

11
12 81. Defendants' conduct was committed with knowing, conscious, wanton, willful,
13 and deliberate disregard for the value of human life and the rights and safety of consumers,
14 including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to
15 punish Defendants and deter them from similar conduct in the future.
16

17 82. WHEREFORE, Plaintiffs demand judgment against Defendants and seek
18 compensatory damages, and exemplary and punitive damages together with interest, the costs of
19 suit and attorneys' fees and such other and further relief as this Court deems just and proper.
20

21 SECOND CLAIM FOR RELIEF

22 Strict Liability

23 83. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if
24 fully set forth herein and further allege as follows.

25 84. At all times relevant to this action, Defendants were suppliers of CELEBREX,
26 placing the drug into the stream of commerce. CELEBREX was expected to and did reach
27 Plaintiffs without substantial change in the condition in which it was manufactured and sold.

28 85. CELEBREX was unsafe for normal or reasonably anticipated use.

 86. CELEBREX was defective in design or formulation because when it left the hands

1 of the manufacturer and/or supplier, it was unreasonably dangerous and more dangerous than an
2 ordinary consumer would expect. CELEBREX was also defective and unreasonably dangerous in
3 that the foreseeable risk of injuries from CELEBREX exceeded the benefits associated with the
4 design and/or formulation of the product.

5 87. Celebrex is unreasonably dangerous: a) in construction or composition; b) in
6 design; c) because an adequate warning about the product was not provided; d) because it does
7 not conform to an express warranty of the manufacturer about the product.

8 88. The characteristics of Celebrex that render it unreasonably dangerous under
9 existed at the time the product left the control of the manufacturer or resulted from a
10 reasonably anticipated alteration or modification of the product.

11 89. The CELEBREX manufactured and supplied by Defendants was also defective
12 due to inadequate warnings, and/or inadequate clinical trials, testing and study, and inadequate
13 reporting regarding the results of the clinical trials, testing and study. Defendants failed to
14 perform adequate testing before exposing Plaintiffs to the medication, testing which would have
15 shown that CELEBREX had the potential to cause serious side effects including strokes like that
16 which affected Plaintiffs.

17 90. The CELEBREX manufactured and supplied by Defendants was defective due to
18 inadequate post-marketing warnings or instructions because, after Defendants knew or should
19 have known of the risk of injuries from CELEBREX, they failed to provide adequate warnings to
20 the medical community and the consumers, to whom they were directly marketing and
21 advertising CELEBREX; and, further, it continued to affirmatively promote CELEBREX as safe
22 and effective.

23 91. CELEBREX was manufactured, distributed, tested, sold, marketed, advertised and
24 promoted defectively by Defendants, and as a direct and proximate cause of Defendants'
25 defective design of CELEBREX, Plaintiffs used CELEBREX rather than other safer and cheaper
26 NSAIDs. As a result, Plaintiffs suffered the personal injuries described above.

27 92. Information given by Defendants to the medical community and to the consumers
28 concerning the safety and efficacy of CELEBREX, especially the information contained in the
advertising and promotional materials, did not accurately reflect the potential side effects of

1 CELEBREX.

2 93. Had adequate warnings and instructions been provided, Plaintiffs would not have
3 taken CELEBREX as they did, and would not have been at risk of the harmful side effects
4 described herein.

5 94. Defendants acted with conscious and deliberate disregard of the foreseeable harm
6 caused by CELEBREX.

7 95. Plaintiffs could not, through the exercise of reasonable care, have discovered
8 CELEBREX's defects or perceived the dangers posed by the drug.

9 96. As a direct and proximate consequence of Defendants' acts, omissions, and
10 misrepresentations described herein, Plaintiffs sustained serious injuries and related losses.
11 Plaintiffs required and will continue to require healthcare and services. Plaintiffs have incurred
12 and will continue to incur medical and related expenses. Plaintiffs also have suffered and will
13 continue to suffer mental anguish, physical pain and suffering, diminished capacity for the
14 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of
15 preexisting conditions and activation of latent conditions, and other losses and damages.
16 Plaintiffs also incurred direct medical losses and costs include care for hospitalization, physician
17 care, monitoring, treatment, medications, and supplies. Plaintiffs have also suffered loss of wages.

18 97. Defendants' conduct was committed with knowing, conscious, wanton, willful,
19 and deliberate disregard for the value of human life and the rights and safety of consumers,
20 including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to
21 punish Defendants and deter them from similar conduct in the future.

22 98. WHEREFORE, Plaintiffs demand judgment against Defendants and seek
23 compensatory damages, and punitive and exemplary damages together with interest, the costs of
24 suit and attorneys' fees and such other and further relief as this Court deems just and proper.

25 **THIRD CLAIM FOR RELIEF**

26 **Breach of Express Warranty**

27 99. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if
28 fully set forth herein and further allege as follows.

100. Defendants expressly represented to Plaintiffs and other consumers and the

1 medical community that CELEBREX was safe and fit for its intended purposes, that it
2 was of merchantable quality, that it did not produce any dangerous side effects,
3 particularly any unwarned-of side effects, and that it was adequately tested.

4 101. These warranties came in the form of:

5 a. Defendants' public written and verbal assurances of the safety and efficacy of
6 CELEBREX;

7 b. Press releases, interviews and dissemination via the media of promotional
8 information, the sole purpose of which was to create an increased demand for CELEBREX,
9 which failed to warn of the risk of injuries inherent to the ingestion of CELEBREX, especially to
10 the long-term ingestion of CELEBREX;

11 c. Verbal and written assurances made by Defendants regarding CELEBREX and
12 downplaying the risk of injuries associated with the drug;

13 d. False and misleading written information, supplied by Defendants, and published
14 in the Physician's Desk Reference on an annual basis, upon which physicians relied in prescribing
15 CELEBREX during the period of Plaintiffs' ingestion of CELEBREX, and;

16 c. advertisements.

17 102. The documents referred to above were created by and at the direction of
18 Defendants.

19 103. Defendants knew or had reason to know that CELEBREX did not conform to these
20 express representations in that CELEBREX is neither as safe nor as effective as represented, and
21 that CELEBREX produces serious adverse side effects.

22 104. CELEBREX did not and does not conform to Defendants' express representations
23 because it is not safe, has numerous and serious side effects, including unwarned-of side effects,
24 and causes severe and permanent injuries.

25 105. Plaintiffs, other consumers, and the medical community relied upon Defendants'
26 express warranties.

27 106. As a direct and proximate consequence of Defendants' acts, omissions, and
28 misrepresentations described herein, Plaintiffs sustained serious injuries and related losses.

1 Plaintiffs required and will continue to require healthcare and services. Plaintiffs have incurred
2 and will continue to incur medical and related expenses. Plaintiffs also have suffered and will
3 continue to suffer mental anguish, physical pain and suffering, diminished capacity for the
4 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of
5 preexisting conditions and activation of latent conditions, and other losses and damages.
6 Plaintiffs also incurred direct medical losses and costs include care for hospitalization, physician
7 care, monitoring, treatment, medications, and supplies. Plaintiffs have also suffered loss of wages.

8 107. Defendants' conduct was committed with knowing, conscious, wanton, willful,
9 and deliberate disregard for the value of human life and the rights and safety of consumers,
10 including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to
11 punish Defendants and deter them from similar conduct in the future.

12 108. WHEREFORE, Plaintiffs demand judgment against Defendants and seek
13 compensatory damages, and punitive and exemplary damages together with interest, the costs of
14 suit and attorneys' fees and such other and further relief as this Court deems just and proper.

15 **FOURTH CLAIM FOR RELIEF**

16 **Breach of Implied Warranty**

17 109. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if
18 fully set forth herein and further allege as follows.

19 110. Defendants manufactured, distributed, advertised, promoted, and sold
20 CELEBREX.

21 111. At all relevant times, Defendants knew of the use for which CELEBREX was
22 intended and impliedly warranted the product to be of merchantable quality and safe and fit for
23 such use.

24 112. Defendants were aware that consumers, including Plaintiffs, would use
25 CELEBREX for treatment of pain and inflammation and for other purposes.

26 113. Plaintiffs and the medical community reasonably relied upon Defendants'
27 judgment and expertise to only sell them or allow them to prescribe CELEBREX only if it was
28 indeed of merchantable quality and safe and fit for its intended use. Consumers, including
Plaintiffs, and the medical community, reasonably relied upon Defendants' implied warranty for

1 CELEBREX.

2 114. CELEBREX reached consumers, including Plaintiffs, without substantial change
3 in the condition in which it was manufactured and sold by Defendants.

4 115. Defendants breached their implied warranty to consumers, including Plaintiffs;
5 CELEBREX was not of merchantable quality or safe and fit for its intended use.

6 116. As a direct and proximate consequence of Defendants' acts, omissions, and
7 misrepresentations described herein, Plaintiffs sustained serious injuries and related losses.
8 Plaintiffs required and will continue to require healthcare and services. Plaintiffs have incurred
9 and will continue to incur medical and related expenses. Plaintiffs also have suffered and will
10 continue to suffer mental anguish, physical pain and suffering, diminished capacity for the
11 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of
12 preexisting conditions and activation of latent conditions, and other losses and damages.
13 Plaintiffs also incurred direct medical losses and costs include care for hospitalization, physician
14 care, monitoring, treatment, medications, and supplies. Plaintiffs have also suffered loss of wages.

15 117. Defendants' conduct was committed with knowing, conscious, wanton, willful,
16 and deliberate disregard for the value of human life and the rights and safety of consumers,
17 including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to
18 punish Defendants and deter them from similar conduct in the future.

19 118. WHEREFORE, Plaintiffs demand judgment against Defendants and seek
20 compensatory damages and punitive and exemplary damages together with interest, the costs of
21 suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

22 **FIFTH CLAIM FOR RELIEF**

23 **Fraudulent Misrepresentation & Concealment**

24 119. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if
25 fully set forth herein and further allege as follows.

26 120. Defendants' superior knowledge and expertise, their relationship of trust and
27 confidence with doctors and the public, their specific knowledge regarding the risks and dangers
28 of CELEBREX, and their intentional dissemination of promotional and marketing information
about CELEBREX for the purpose of maximizing its sales, each gave rise to the affirmative duty

1 to meaningfully disclose and provide all material information about CELEBREX's risks and
2 harms to doctors and consumers.

3 121. Defendants made fraudulent affirmative misrepresentations with respect to
4 CELEBREX in the following particulars:

5 a. Defendants represented through their labeling, advertising, marketing materials,
6 detail persons, seminar presentations, publications, notice letters, and regulatory submissions that
7 CELEBREX had been tested and found to be safe and effective for the treatment of pain and
8 inflammation; and

9 b. Defendants represented that CELEBREX was safer than other alternative
10 medications.

11 122. Defendants made affirmative misrepresentations; and fraudulently, intentionally
12 and/or recklessly concealed material adverse information regarding the safety and effectiveness of
13 CELEBREX.

14 123. Defendants made these misrepresentations and actively concealed adverse
15 information at a time when Defendants knew or had reason to know that CELEBREX had defects
16 and was unreasonably dangerous and was not what Defendants had represented to the medical
17 community, the FDA and the consuming public, including Plaintiffs.

18 124. Defendants omitted, suppressed and/or concealed material facts concerning the
19 dangers and risk of injuries associated with the use of CELEBREX including, but not limited to,
20 the cardiovascular, cerebrovascular, and other serious health risks. Furthermore, Defendants'
21 purpose was willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the
22 serious nature of the risks associated with the use of CELEBREX in order to increase its sales.

23 125. The representations and concealment were undertaken by Defendants with an
24 intent that doctors and patients, including Plaintiffs, rely upon them.

25 126. Defendants' representations and concealments were undertaken with the intent of
26 defrauding and deceiving Plaintiffs, other consumers, and the medical community to induce and
27 encourage the sale of CELEBREX.

28 127. Defendants' fraudulent representations evinced their callous, reckless, willful, and
depraved indifference to the health, safety, and welfare of consumers, including Plaintiffs.

1 128. Plaintiffs' physician and Plaintiffs relied on and were induced by Defendants'
2 misrepresentations, omissions, and/or active concealment of the dangers of CELEBREX in
3 selecting CELEBREX treatment.

4 129. Plaintiffs and the treating medical community did not know that the
5 representations were false and were justified in relying upon Defendants' representations.

6 130. Had Plaintiffs been aware of the increased risk of side effects associated with
7 CELEBREX and the relative efficacy of CELEBREX compared with other readily available
8 medications, Plaintiffs would not have taken CELEBREX as he did.

9 131. As a direct and proximate consequence of Defendants' acts, omissions, and
10 misrepresentations described herein, Plaintiffs sustained serious injuries and related losses.
11 Plaintiffs required and will continue to require healthcare and services. Plaintiffs have incurred
12 and will continue to incur medical and related expenses. Plaintiffs also have suffered and will
13 continue to suffer mental anguish, physical pain and suffering, diminished capacity for the
14 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of
15 preexisting conditions and activation of latent conditions, and other losses and damages.
16 Plaintiffs also incurred direct medical losses and costs include care for hospitalization, physician
17 care, monitoring, treatment, medications, and supplies. Plaintiffs have also suffered loss of wages.

18 132. Defendants' conduct was committed with knowing, conscious, wanton, willful,
19 and deliberate disregard for the value of human life and the rights and safety of consumers,
20 including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to
21 punish Defendants and deter them from similar conduct in the future.

22 133. WHEREFORE, Plaintiffs demand judgment against Defendants and seek
23 compensatory damages, and punitive and exemplary damages together with interest, the costs of
24 suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

25 **SIXTH CLAIM FOR RELIEF**

26 **Unjust Enrichment**

27 134. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if
28 fully set forth herein and further allege as follows.

135. At all times relevant to this action, Defendants were the manufacturers, sellers,

1 and/or suppliers of CELEBREX.

2 136. Plaintiffs paid for CELEBREX for the purpose of managing their pain safely and
3 effectively.

4 137. Defendants have accepted payment from Plaintiffs for the purchase of
5 CELEBREX.

6 138. Plaintiffs did not receive the safe and effective pharmaceutical product for which
7 she paid.

8 139. It is inequitable and unjust for Defendants to retain this money because Plaintiffs
9 did not in fact receive the product Defendant represented CELEBREX to be.

10 140. WHEREFORE, Plaintiffs demand judgment against Defendants and seeks
11 equitable relief, the costs of suit and attorneys' fees, and such other and further relief as this Court
12 deems just and proper.

13 **PRAYER FOR RELIEF**

14 WHEREFORE, Plaintiffs request the following relief:

- 15 1. General damages in excess of the jurisdictional amount of this Court;
- 16 2. Consequential damages;
- 17 3. Disgorgement of profits;
- 18 4. Restitution;
- 19 5. Damages for loss of consortium, care, comfort, society and companionship in an
20 amount within the jurisdiction of this Court and according to proof;
- 21 6. Punitive and exemplary damages;
- 22 7. Pre-judgment and post-judgment interest as provided by law;
- 23 8. Recovery of Plaintiffs' costs including, but not limited to, discretionary Court
24 costs of these causes, and those costs available under the law, as well as expert fees and attorneys'
25 fees and expenses, and costs of this action; and
- 26 9. Such other and further relief as the Court deems just and proper.

27 Dated: August 22, 2007

28 Respectively submitted,

1 By: Navan Ward Jr.

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14 Attorneys for Plaintiff

15 **DEMAND FOR JURY TRIAL**

16 Plaintiffs demand a trial by jury on all claims so triable in this action.

17 Dated: August 22, 2007

18 Respectfully submitted,

19 By: Navan Ward Jr.

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